

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/19/2009 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. **Claims 1-4, 6-18, 20-29, 31, 33, 34, 43, 73-78, 82-84 and 88-96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grayzel (4,796,629) in view of Vigil et al. (5,336,234).**

Grayzel discloses a balloon catheter including a balloon (40) that has striped portions (1050) encapsulated therein. The striped portions run the length of the balloon, and are tapered at the ends so that they conform to the shape of the balloon (see column 6, lines 14-23). Because they conform to the shape of the balloon, they will be substantially straight in the collapsed configuration, and at least slightly deformed in the expanded configuration due to the tapered portions of the balloon. The striped portions are parallel to the axis of the balloon and are evenly

spaced circumferentially about the balloon. However, Grayzel fails to disclose cutting elements attached to the balloon. Attention is drawn to Vigil et al., who teach the use of cutting elements that are disposed on a balloon (see figures 2-4) to further assist in dilation of a stenotic portion of a vessel. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the cutting elements of Vigil et al. on the balloon of Grayzel to assist in dilation of a stenotic portion of a vessel.

4. Examiner notes that Vigil et al. shows the claimed furrow/flap configuration (see figure 2).

5. Further, the combination of Grayzel and Vigil et al. does not teach the cutting elements be centered over the striped portions. However, it has been held that choosing from a finite number of solutions to obtain a predictable result is a rationale for determining obviousness. *KSR International Co. v. Teleflex Inc. (KSR)*, 550 U.S. ___, 82 USPQ2d 1385 (2007). It can be seen that there are only a finite number of positions the blades can be placed on the exterior surface of the balloon, with one of the various positions being the blades centered over the striped portions. Therefore, it would have been obvious one of ordinary skill in the art to have the cutting elements centered over the striped portions since this is one of a limited number of possible positions for the cutting elements to be located relative to the striped portions.

6. Regarding claims 6-9, 11-13, and 23-30, the combination of Grayzel and Vigil et al. does not disclose a specific distensibility of the striped portion relative to the balloon. However, it has been held that where the general conditions of a claim are disclosed in

the prior art, it is not inventive to discover the optimum or workable ranges. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

7. Regarding claims 10 and 20, the claims are written in product-by-process form. It has been held that even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)

8. Regarding claims 88-93, Grayzel discloses the material of the striped portions can vary (see column 5, lines 17-19) if desired. Further, the combination set forth above includes 4 cutting elements from Vigil and 6 striped portions from Grayzel, leaving some of the striped portions without a cutting element centered over it.

9. **Claims 30 and 85-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grayzel (4,796,629) in view of Vigil et al. (5,336,234) as applied to claims 1, 14 and 43 above, and further in view of Roychowdhury (5,587,125).**

10. Regarding claim 30, the combination of Grayzel and Vigil et al. does not disclose the striped portion is a liquid crystal polymer. Attention is drawn to Roychowdhury, who teaches that liquid crystal polymers may be used in balloons to provide exceptional tensile qualities (see column 5, lines 8-25). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the striped

portions of the combination of Grayzel and Vigil et al. of liquid crystal polymer, as taught by Roychowdhury, to provide exceptional tensile qualities to the balloon.

11. Regarding claims 85-87, the combination of Grayzel and Vigil et al. does not disclose the first material (the balloon) comprises a compatibilizing material. Attention is again drawn to Roychowdhury, who teaches the use of compatibilizing materials to help the balloon bond to the catheter body (see column 5, lines 26-37). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the compatibilizing material of Roychowdhury with the balloon of the combination of Grayzel and Vigil et al. to enhance the bond between the balloon and the catheter body.

12. **Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grayzel (4,796,629) in view of Vigil et al. (5,336,234) as applied to claim 14 above, and further in view of Spears (5,092,841).** The combination of Grayzel and Vigil et al. does not disclose the balloon comprises an inorganic additive. Attention is drawn to Spears, who teaches the use of an inorganic salt drug to provide treatment to the vessel (see column 7, lines 56-62). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the inorganic additive of Spears on the balloon of the combination of Grayzel and Vigil et al. to provide treatment to the vessel.

Response to Arguments

13. Applicant's arguments with respect to claims 1, 14 and 43 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan J. Severson whose telephone number is (571) 272-3142. The examiner can normally be reached on Monday - Friday 8:30-5:00.

15. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ryan J. Severson/
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1/14/10

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1/15/10